

REMARKS

Applicants respectfully request favorable reconsideration in view of the herewith-presented amendments and remarks. Claims 56, 80 and 91 have been amended to correct several typographical errors. The amendments raise new issues of patentability.

Claims 39-58, 62, 80, 82, 89, 91 and 97-100 are pending in this application. Claims 80 and 91 have been amended to correct several typographical errors. Claims 39, 62 and 80 has also been amended. The amendments raise no new issues of patentability and contain no new subject matter.

35 U.S.C. §102

Claims 39, 40-44, 55, 56, 62, 89 and 91 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Gossen et al. (U.S. Patent No. 5,602,300). The Applicants respectfully traverse this rejection.

The Gossen reference describes tagging nucleic acids using an internal nucleic acid tag, preferably a lacZ operator sequence. This nucleic acid tag is incorporated into each plasmid in the sample DNA. Gossen then requires an additional step where an antibody (or some other proteaceous binding material) is bound to the matrix which then interacts with the nucleic acid tag. Therefore, in Gossen, the method for separating nucleic acids relies on an internal nucleic acid tag that binds to an antibody that is bound to the matrix. Gossen does not teach or suggest using an external protein tag for the isolation of nucleic acids wherein the protein tag directly binds to the matrix.

The instant claims are directed to methods of separating nucleic acid molecules into populations. The methods require the populations be tagged with a protein capable of being

immobilized on a matrix and the matrix selectively and directly binds to the protein tags. Claim 39 of the instant application specifically recites a population of nucleic acid molecules to be tagged "with a protein". Claim 39 also requires that the matrix must be one which "selectively binds said protein" "whereby said protein interacts directly with the matrix". Neither of these features are disclosed in the Gossen reference. Gossen describes a plasmid that must possess a "lacZ operator sequence as a marker gene" (column 2, line 64). This "operator sequence" is a nucleotide sequence; *it is not a protein tag*. The plasmid is therefore not tagged with a protein.

Additionally, the Gossen reference describes a "matrix" that is a solid particle coated with a material which is proteaceous in nature, *i.e.*, an antibody or a LacZ repressor. Hence, the Gossen matrix is one which is coated with "substantially proteinaceous or protein material". Therefore, rather than selectively and directly binding specific protein tags as claimed; the matrix described in Gossen is designed to bind to the nucleotide sequence tag, which is the lacZ operator sequence.

Consequently, it can be seen that the DNA plasmid referred to in the Gossen reference is not tagged with a protein tag; and the matrix used is not one which "selectively bind said protein" "whereby said protein interacts directly with the matrix". Hence two essential features of claim 39 are not taught or suggested in the Gossen reference.

Similarly, claims 62 and 80 also require use of a protein tag and a matrix capable of selectively and directly binding these protein tags. Neither of these elements are taught or suggested in the Gossen reference. Thus, the subject matter of claims 62 and 80 are also novel for the reasons given above.

A claim is anticipated only if "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros.*

v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Because Gossen does not teach or suggest a protein tag or that the matrix is specifically designed to bind directly to these protein tags, applicants assert that Gossen does not anticipate independent claim 39 nor claims 43, 44, 55 or 56, all of which depend from claim 39.

Claims 40, 41, 42, 43, 44, 55 and 56 are all dependent, directly or indirectly, on claim 39 and hence the subject matter of these claims is also novel for the reasons given above. Similarly, claims 89 and 91 are dependent on claim 80 and novel for the reasons discussed above.

It is respectfully asserted therefore that the subject matter of claim 39, 40, 41-44, 55, 56, 62, 89 and 91 are novel over the Gossen reference. Applicants respectfully request reconsideration and withdrawal of this §102(b) rejection.

35 U.S.C. §103(a): Gossen in view of Seed

Claims 45, 46, 80-86 and 93 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gossen et al. (US 5,602,300) as applied to claims 39, 43 and 44, and further in view of Seed et al. (EP 0580305). Applicants respectfully traverse this rejection.

As discussed above, two essential features of claims 45, 46, 80-86 and 93 are not disclosed in Gossen, i.e. the DNA plasmid referred to in Gossen is not tagged with a protein tag (rather the tag is a nucleic acid sequence) and the matrix does not directly bind the protein tag because there is none. There is no teaching or suggestion in Gossen to tag a nucleic acid population with a protein; and then to isolate that population on a matrix which selectively or directly binds the protein tag. In contrast, Gossen discloses the use of solid particles to which are

bound proteaceous material; and the use of such particles to isolate plasmids containing a nucleic acid sequence tag (i.e. lacZ operator).

As mentioned by the Examiner, Seed discloses a matrix for separating nucleic acids in a cartridge device. Seed does not, however, teach or suggest the tagging of a nucleic acid population with a protein and then the isolation of that population on a matrix which selectively binds the protein tags which is missing from the primary reference (Gossen).

Therefore, neither Gossen nor Seed teach or suggest that the tag must be a protein or that the matrix specifically and directly binds the protein tag as required by the present invention. Thus, Applicants assert the Examiner has failed to establish a *prima facie* case of obviousness for these claims in respect to Gossen in view of Seed.

Therefore, applicants respectfully request reconsideration and withdrawal of this §103(a) rejection. The rejection directed to claim 93 is believed moot, because this claim is currently cancelled.

35 U.S.C. §103(a): Gossen in view of Davis

Claims 47-54 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gossen et al. (US 5,602,300) as applied to claim 39, and further in view of Davis et al. (WO95/12115). Applicants respectfully traverse this rejection.

Claims 47-54 are all dependent, directly or indirectly, on claim 39. As discussed above, it can be seen that two essential features of claims 47-54 are not disclosed in Gossen. The DNA plasmid referred to in the Gossen reference is not tagged with a protein tag, and the matrix does not directly and selectively bind protein tags.

There is no teaching or suggestion in Gossen to tag a nucleic acid population with a protein; and then to isolate that population on a matrix which selectively and directly binds that protein tag. In contrast, Gossen discloses the use of solid particles to which are bound to a proteaceous material; and the use of such particles to isolate plasmids containing a nucleic acid tag nor would such a method be obvious to the skilled artisan in view of Gossen or Davis.

Davis relates to the amplification of DNA fragments by using the polymerase chain reaction technique (PCR) and the detection of mutations. However, Davis does not teach or suggest the tagging of a nucleic acid population with a protein and then the isolation of that population on a matrix which directly and selectively bind protein tag. Therefore Davis does not remedy the deficiencies of Gossen.

Neither Gossen nor Davis teach or suggest that the tag must be a protein or that the matrix specifically or directly bind protein tags as required by the present invention. Therefore the Examiner has failed to establish a *prima facie* case of obviousness for these claims in respect to Gossen in view of Davis.

Therefore, applicants respectfully request reconsideration and withdrawal of this §103(a) rejection.

35 U.S.C. §103(a): Gossen in view of Dower

Claims 47-54 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gossen et al. (US 5,602,300) as applied to claim 39, and further in view of Dower et al. (US 5,427,908). Applicants respectfully traverse this rejection.

Claims 47-54 are all dependent, directly or indirectly, on claim 39. As discussed above, it can be seen that two essential features of claims 47-54 are not disclosed in Gossen. The DNA plasmid referred to in the Gossen reference is not tagged with a protein tag, and the matrix does not directly and selectively bind protein tags.

There is no teaching or suggestion in Gossen to tag a nucleic acid population with a protein; and then to isolate that population on a matrix which selectively and directly binds that protein tag. In contrast, Gossen discloses the use of solid particles to which are bound to a proteaceous material; and the use of such particles to isolate plasmids containing a nucleic acid tag nor would such a method be obvious to the skilled artisan in view of Gossen or Dower.

Dower relates to the *in vitro* packaging of bacteriophage particles. However, Dower does not teach or suggest the tagging of a nucleic acid population with a protein and then the isolation of that population on a matrix which directly and selectively binds these protein sequence tags. Therefore the Dower reference does not remedy the deficiencies of the Gossen reference.

Neither Gossen nor Dower teach or suggest that the tag must be a protein or that the matrix directly and specifically bind protein tags as required by the present invention. Therefore the Examiner has failed to establish a *prima facie* case of obviousness for these claims in respect to Gossen in view of Dower.

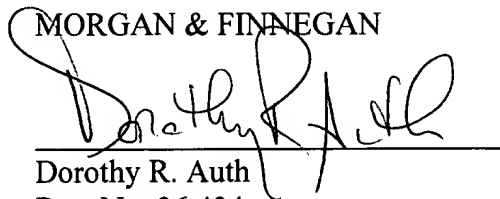
Therefore, applicants respectfully request reconsideration and withdrawal of this §103(a) rejection.

CONCLUSION

It is respectfully submitted that all of the pending claims are now allowable and early favorable action in that regard is solicited. In the event any issues remain that could potentially be resolved by telephone, the Examiner is urged to contact the undersigned at the number below. Should any additional fee(s) be required for the entry of this Amendment, the Commissioner is hereby authorized to charge Deposit Account No. **13-4500**, Order No. **4290-4000**.

Respectfully submitted,

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Dated: September 6, 2006

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